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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/816,814	03/23/2001	Jorg J. Goronzy	07039-251001	6147

26191 7590 12/05/2003

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EXAMINER	
BASI, NIRMAL SINGH	
ART UNIT	**PAPER NUMBER**
1646	

DATE MAILED: 12/05/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/816,814	GORONZY ET AL.	
	Examiner	Art Unit	
	Nirmal S. Basi	1646	

-- The MAILING DATE of this communication appears on the cov r she t with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *02 September 2002*.

2a)☒ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-15,17-33 and 36-41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 3-15,17-33,36-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Amendment filed 9/2/02 has been entered.

Claim Rejection, 35 U.S.C. 112

2. Claims 1, 3-15, 17-33, 36-41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "elevated" in claims 1, 6-9, 13, 21, 22, 23, 24, 36-41 is a relative term which renders the claim indefinite. The term elevated is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The specification discloses "elevated level" as used herein with respect to the level of a CD21L polypeptide, a lymphotoxin-B polypeptide or a chemoattractant polypeptide is any level that is greater than a reference level for a CD21L polypeptide, a lymphotoxin-B polypeptide or a chemoattractant polypeptide. The specification discloses term reference level as used herein with respect to the level of a CD21L polypeptide, a lymphotoxin-B polypeptide or a chemoattractant polypeptide is any level that is greater than a reference level for a CD21L polypeptide, a lymphotoxin-B polypeptide or a chemoattractant polypeptide typically expressed by mammals having mild RA. There is no disclosure of the typical level of expression of CD21L polypeptide, a lymphotoxin-B polypeptide or a chemoattractant polypeptide so as to allow the elevated levels to be determined. Further there is no quantitative measure of when a condition is mild RA as compared to severe RA. Further, the definition of

severe does not encompass lymphotoxin-alpha polypeptide, SLC polypeptide, DC-CK 1 polypeptide, BLC polypeptide or MCP-1 polypeptide.

Claims 3-5, 10-12, 14-20, 25-35 are rejected for depending on an indefinite base claim and fail to resolve the issues raised above.

Claim Rejections, 35 U.S.C. 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 3-5, 7-15, 17-20, 22-33, 38, 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goronzy et al (US Patent No. 6555,320 B1) in view of Li et al (US Patent No. 6,075,124) and further in view of

Karin et al (US Patent 6,075,124), Kara et al (US Patent 6,088,695) and Coli et al (US Patent 6,018,713) . Goronzy teaches an invention involving methods and materials for evaluating rheumatoid arthritis (RA)in a patient and specifically classifying a RA condition as diffuse, follicular, or granulomatous. In addition, the invention provides methods and materials for determining if an individual suffering from a rheumatoid arthritis condition will develop severe disease (see abstract). Goronzy discloses RA is systemic inflammatory disease that primarily manifests as synovial inflammation of diarthrodial joints and the level of particular cytokines within tissue can be used to classify a RA condition, the granulomatous patients being more susceptible to severe RA disease. The cytokines, Il-4, Il-10 and IFN-γ, Il-1β, TNF-α and TBF-1 were used to determine the severity of RA in a patient by comparing to a reference level (column 3, Table 7 and claims). Goronzy does not disclose a method of assisting a person in determining the severity of an arthritis condition in a mammal or communicating information about the presence or absence of said at least one marker in said sample to said person, wherein the presence of said at least one marker indicates that said arthritis condition is severe. Further Goronzy does not specifically disclose that the presence of at least on marker indicates that the RA condition is severe.

Li teaches MCP-1(monocyte chemotactic protein) levels were found to be significantly higher in synovial fluid from RA patients compared to synovial fluid form osteoarthritis patients or from patents with other arthritides (column 2).

Karin discloses the use of cytokines, MIP-1α, MCO-1, MIP-1β, RANTES and TNF-α, to treat RA by inducing formation of antibodies to said cytokines, wherein said antibodies reduce an vivo activity of an endogenous cytokine of said cytokines, to thereby treating RA (see claims and Examples). Karin also discloses the use of rats in evaluating the effects of cytokines in RA treatment.

Kara teaches a system and method for communicating medical records. It is also disclosed patients undergo tests, the results of which are gathered by the diagnosing physician and then evaluated.

Coli et al discloses an integrated system and method for ordering and cumulative results reporting of medical tests.

It would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made to use the chemoattractant polypeptides (cytokines) disclosed above by
Goronzy, Li and Karin to determine the severity of RA in a mammal said method comprising determining whether or not a sample from said mammal contains at least one marker, Il-4, Il-10 and IFN-γ, Il-1β, TNF-α and TBF-1 (Goronzy), MCP-1 (Li) or MIP-1α, MCO-1, MIP-1β, RANTES and TNF-α (Karin) wherein the presence of at least one marker indicates that said arthritis condition is severe and further communicating information about the presence or absence of said at least one marker in said sample to a person (doctor scientist etc) as disclosed by Kara et al and Coli et al. The ordinary artisan would have been motivated to measure the levels of the markers Il-4, Il-10 and IFN-γ, Il-1β, TNF-α, TBF-1, MCP-1, MIP-1α, MCO-1, MIP-1β, RANTES in a mammal synovial tissue sample

because prior art teaches that elevation of said markers, either alone or in combination is an indicator of the severity of the RA condition. Further measurement of the markers Il-4, Il-10 and IFN-γ, Il-1β, TNF-α, TBF-1, MCP-1, MIP-1α, MCO-1, MIP-1β, RANTES is well known in the art and is routinely carried out by laboratory technicians. Laboratory technicians routinely report their results to the medical doctor who in turn evaluates the results and informs the patient of the test results. The protocol of testing samples for chemokines, reporting the results to a physician (directly or indirectly), evaluating the results and then communicating the results to other parties (directly or indirectly is well known in the art) and is exemplified by Kara et al and Coli et al.

The ordinary artisan would have expected success for determining the severity of RA by measuring the markers Il-4, Il-10 and IFN-γ, Il-1β, TNF-α, TBF-1, MCP-1, MIP-1α, MCO-1, MIP-1β, RANTES because said markers have been associated with RA and antibodies to some of said markers have been used to treat RA. Further the method of Kara and Coli could be used to communicate the results of the severity of RA analysis because they relate to an improved system and method for on-line ordering of medical tests in a health care network and method for uniformly recording and reporting test results.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nirmal S. Basi whose telephone number is 703-308-9435. The examiner can normally be reached on 9:00 AM-5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on 703-308-6564. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Nirmal S. Basi
Art Unit 1646
01/12/20023

MICHAEL PAK
PRIMARY EXAMINER